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SynCardia SYSTEMS, INC.

June 29, 2007

Steve E. Phurrough, M.D., M.P.A., Director
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mailstop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for National Coverage Determination Concerning Biventricular Replacement Device for Bridge to Transplant Indication

Dear Dr. Phurrough:

By this letter, SynCardia Systems, Inc. (SynCardia) submits a formal request for national coverage of a biventricular replacement device to address the use of such a device solely as a bridge to transplant. SynCardia believes that there is adequate evidence for the Centers for Medicare and Medicaid Services (CMS) to conclude that the CardioWest™ temporary Total Artificial Heart (TAH-t) as a biventricular replacement device is reasonable and necessary when used as a bridge to transplant in certain patients.

SynCardia recognizes that the marketed name of the TAH-t could be viewed as implicating CMS' national noncoverage determination (NCD) on artificial hearts from 1986. In our view, that coverage decision should not apply to a biventricular replacement device such as the TAH-t that replaces only the ventricles, but leaves other portions of the heart (e.g., the atria) intact. The agency could make this clear through a coverage provision in an interpretive manual that states that a device that does not replace the ventricles and the atria is not an "artificial heart" under Medicare. *See* Program Integrity Manual, Chapter 13, § 13.1.2. Under such an approach, CMS would not have to undertake a national coverage analysis for the TAH-t since there is no national coverage policy on biventricular replacement devices, and therefore coverage of these devices would be left to contractor discretion. Should the agency believe that the TAH-t is an artificial heart for Medicare coverage purposes, or that an NCD is required in order to define what is and is not an artificial heart, we believe that there is sufficient evidence to support the opening of a reconsideration of the 1986 artificial heart coverage decision and approve coverage for artificial hearts when used as a bridge to transplant.

As you know, the TAH-t is the only biventricular replacement device that is approved as a bridge to transplant by the Food and Drug Administration (FDA). In previous materials submitted to CMS, we focused on the use of the TAH-t for its labeled indication using the currently approved driver, which weighs approximately 350 pounds. As you also know, we have developed a new driver that weighs only 45 pounds, and we are pursuing a Category B Investigational Device Exemption (IDE) designation with the FDA for use of the TAH-t with the new driver. This

revised submission includes details about the new driver and the IDE trial we plan to conduct. Based on our experience with a portable driver in Europe, its size would allow patients receiving the TAH-t to leave the hospital while awaiting a heart transplant, which has important clinical benefits. We note also that the new driver would be used for the same indication and for the same patient population as we use the current driver. The attached request includes a discussion concerning data on use of the TAH-t since the completion of the premarket approval trial demonstrating similar results to those seen for patients in that trial, and superior to results with ventricular assist devices (VADs) in patients in biventricular failure.

SynCardia is committed to seeking coverage of the TAH-t only when used as a bridge to transplant. That is the only approved indication for the TAH-t and that is the only indication that would be studied in the IDE trial of the new driver that we are pursuing with the FDA. While there is another FDA approved biventricular replacement device, it is approved for a different indication – destination therapy. The TAH-t is the only device approved for the bridge to transplant indication. Given that CMS typically approaches national coverage determinations on an indication specific basis – exemplified by VADs, where there have been separate national coverage analyses for use of VADs as a bridge to transplant and for use as destination therapy – we believe it is appropriate and consistent with past precedent for CMS to separately consider coverage for biventricular replacement devices only for use as a bridge to transplant.

An examination of the TAH-t as a bridge to transplant would involve the agency's reviewing the evidence of the on-label use of an FDA approved device. While we are aware that the agency is currently reconsidering its clinical research policy through the national coverage determination process, we do not believe that coverage of biventricular replacement devices as a bridge to transplant implicates this policy. In our view, adequate evidence exists to conclude that this FDA approved device is reasonable and necessary for the indicated patient population. The clinical trial that we are contemplating involves an IDE trial using the new driver and we are hopeful of obtaining a Category B IDE designation for the new driver. In that circumstance, coverage related to the trial would be driven by the IDE regulations, not the clinical research policy.

SynCardia is anxious to be able to bring the technology to Medicare beneficiaries and we see different vehicles that the agency could utilize to authorize coverage for the device – a coverage provision in an interpretive manual; a new national coverage determination; or reconsideration of an existing national coverage determination. Some of the most prominent hospitals in the United States share the desire to utilize the TAH-t, as reflected by letters that are include with our submission. To SynCardia, the vehicle for coverage is less important than securing coverage, and we are prepared to proceed through whatever route the agency decides to be appropriate.

We look forward to working with you in that regard. Please do not hesitate to contact me at (520) 545-1234 Ext. 1203 with any questions.

Respectfully,

Carole E. Marcot
Vice President
Regulatory Affairs and Quality

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Enclosures

SynCardia SYSTEMS, INC.